DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 19, 2014

GE Medical Systems, LLC
% Mr. David Duersteler
Regulatory Affairs Leader
3000 North Grandview Blvd.
WAUKESHA WI 53188

Re: K141074
Trade/Device Name: CortexID Suite
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: September 12, 2014
Received: September 15, 2014

Dear Mr. Duersteler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141074

Device Name
CortexID Suite

Indications for Use *(Describe)*
CortexID software has been developed to aid physicians in the evaluation of patient pathologies via assessment and quantification of PET brain scans.

The software aids in the assessment of human brain PET scans enabling automated analysis through quantification of tracer uptake and comparison with the corresponding tracer uptake in normal subjects. The resulting quantification is presented using volumes of interest, voxel-based or 3D stereotactic surface projection maps of the brain. The package allows the user to generate information regarding relative changes in PET-FDG glucose metabolism.

CortexID Suite additionally allows the user to generate information in PET brain amyloid load between a subject's images and a normal database, which may be the result of brain neurodegeneration.

PET co-registration and fusion display capabilities with CT and MR allow PET findings to be related to brain anatomy and offers visualization of structural abnormalities, which may result from brain injury, trauma, disorder, disease or dysfunction, such as subdural hematoma, tumor, stroke, or cerebrovascular disease, etc.

CortexID Suite may aid physicians in the image interpretation process of PET studies conducted on patients being evaluated for cognitive impairment, or other causes of cognitive decline, and is an adjunct to other diagnostic evaluations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 23, 2014
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd. Waukesha, WI 53188, USA
Primary Contact Person:	Peter Uhlir Regulatory Affairs Leader Tel: 00 36 23 410121 Fax: 1-847-277-4506
Secondary Contact Person:	Jeme Wallace Regulatory Affairs Director GE Healthcare Tel: 1-847-277-4468 Fax: 1-847-277-4506
Device Trade Name:	CortexID Suite
Common/Usual Name:	CortexID Suite
Classification Names: Product Code:	21CFR 892.1200, Radiology KPS
Predicate Device(s):	K062393 - CortexID (originally called GE Vantage PET Neuro)
Device Description:	CortexID, image analysis software, has been developed to aid clinicians in the assessment and quantification of pathologies derived from PET scans. The software enables the display, co-registration, and fusion of PET images with those from other modalities. It enables automated quantitative and statistical analysis of tracer uptake by registration to a standard template space and comparing intensity values. Additionally, CortexID assists with comparison of the activity in defined brain regions of individual scans relative to normal activity values as found in normal subjects. Quantification is presented using volumes of interest, voxel-based or 3D stereotactic surface projection maps of the brain.

	Key features of the CortexID Suite include: a. Integrated platform for FDG and Beta Amyloid analysis b. PET-MR and PET-CT registration and fusion c. Automatic reorientation and standardization d. 3D SSP, Voxel based images and VOI statistics e. Comparison with normals databases f. Longitudinal Analysis g. Q.Check h. Summing input dynamic PET scan i. Exam Summary (integrated report) j. Easy Export k. Multiple Reference Regions l. Reoreintation m. Region Overlay n. Fully Customizable Interface o. Preset Presentations p. MR Template Image The CortexID Suite is also made available as a standalone post processing application on the AW VolumeShare 5 workstation (K110834) that hosts advanced image processing applications.
Indications for Use / Intended Use:	CortexID software has been developed to aid physicians in the evaluation of patient pathologies via assessment and quantification of PET brain scans. The software aids in the assessment of human brain PET scans enabling automated analysis through quantification of tracer uptake and comparison with the corresponding tracer uptake in normal subjects. The resulting quantification is presented using volumes of interest, voxel-based or 3D stereotactic surface projection maps of the brain. The package allows the user to generate information regarding relative changes in PET-FDG glucose metabolism. CortexID Suite additionally allows the user to generate information in PET brain amyloid load between a subject's images and a normal database, which may be the result of brain neurodegeneration. PET co-registration and fusion display capabilities with CT and

	MR allow PET findings to be related to brain anatomy and offers visualization of structural abnormalities, which may result from brain injury, trauma, disorder, disease or dysfunction, such as subdural hematoma, tumor, stroke, or cerebrovascular disease, etc. CortexID Suite may aid physicians in the image interpretation process of PET studies conducted on patients being evaluated for cognitive impairment, or other causes of cognitive decline, and is an adjunct to other diagnostic evaluations.
Technology:	The CortexID Suite software employs the same fundamental scientific technology as its predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The CortexID Suite software complies with NEMA PS 3.1 - 3.20 (2011) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard. CortexID Suite employs the same fundamental scientific technology as its predicate device, CortexID. CortexID Suite uses the equivalent DICOM image data input requirements. It has equivalent display, formatting, archiving and visualization technologies compared to the predicate device. CortexID Suite utilizes essentially the same methodology to quantify and assess uptake of FDG and beta amyloid tracers. The information is presented using volumes of interest, voxel-based or 3D stereotactic surface projection maps of the brain. CortexID Suite utilizes existing PET & CT co-registration and fusion technologies and provides for PET & MR co-registration and fusion capabilities. Thorough testing of these capabilities has not raised any safety or effectiveness issues. The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Integration testing (System verification) ▪ Performance testing (Bench testing, verification) ▪ Safety testing (Verification) Summary of Clinical tests: The subject of this premarket submission, CortexID Suite software did not require clinical studies to support substantial equivalence since it introduces analysis of new PET image contrast agents only. The clinical utility for the analysis of the new image processing has not been studied since modification

	does not significantly affect the clinical safety and performance. The substantial equivalence determination is based on the software documentation for a MODERATE level of concern device.
Conclusion:	GE Healthcare considers the CortexID Suite software application to be as safe, as effective, and performance is substantially equivalent to the predicate device.